

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA**

KARL STORZ ENDOSCOPY)
AMERICA, INC.,)
)
Plaintiff and Counterclaim)
Defendant,)
)
v.) Case No. 2:12-cv-02716-KOB
)
INTEGRATED MEDICAL)
SYSTEMS INTERNATIONAL,)
INC.,)
)
Defendant and Counterclaim)
Plaintiff)

**DEFENDANT'S ANSWER, AFFIRMATIVE DEFENSES
AND COUNTERCLAIMS**

Defendant STERIS Instrument Management Services, Inc., f/k/a Integrated Medical Systems International, Inc. (“IMS”), states as follows for its Answer and Affirmative Defenses to the First Amended Complaint for Patent Infringement [Doc. 63] (hereinafter “First Amended Complaint”) filed by Plaintiff Karl Storz Endoscopy-America, Inc. (“Plaintiff”):

1. IMS lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the First Amended Complaint and therefore denies them.

2. IMS admits the allegations of paragraph 2 of the First Amended Complaint, except that it states that its principal place of business is located at 3316 2nd Avenue North, Birmingham, Alabama 35222.

3. In response to the allegations of paragraph 3 of the First Amended Complaint, IMS admits that this is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, et seq., but denies that it has committed any act of infringement, denies that Plaintiff is entitled to any damages or injunctive relief and denies the legal sufficiency of the First Amended Complaint.

4. IMS admits the allegations of paragraph 4 of the First Amended Complaint.

5. In response to the allegations of paragraph 5 of the First Amended Complaint, IMS states that it does not contest the propriety of venue in this judicial district but denies that any wrongful events have occurred which give rise to this action or that Plaintiff has suffered harm in this judicial district.

6. IMS admits the allegations of paragraph 6 of the First Amended Complaint, except that it denies that it provides reconstruction services.

7. In response to the allegations of paragraph 7 of the First Amended Complaint, IMS admits that U.S. Patent No. 7,530,945 ("the '945 Patent") was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on May 12, 2009 and that a copy of the '945 Patent is attached as Ex. A to the First

Amended Complaint. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the First Amended Complaint and therefore denies them.

8. In response to the allegations of paragraph 8 of the First Amended Complaint, IMS admits that U.S. Reissued Patent No. RE47,044 (“the ’044 Patent”) was reissued by the USPTO on September 18, 2018 but states that the ’044 Patent as reissued contains clerical errors in claims 8-13 and that Plaintiff has requested that the USPTO issue a certificate of correction to correct such errors. Thus, IMS denies that an accurate copy of the ’044 Patent is attached as Ex. B to the First Amended Complaint. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8 and therefore denies them.

9. In response to the allegations of paragraph 9 of the First Amended Complaint, IMS denies that it has committed any act of infringement or otherwise unlawfully exploited Plaintiff’s technology. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 and therefore denies them.

10. In response to the allegations of paragraph 10 of the First Amended Complaint, IMS admits that it repairs and sells medical products, including endoscopes, but denies the remaining allegations of paragraph 10, including that it

reconstructs endoscopes and that the endoscopes it repairs and/or sells have been modified to be of inferior quality, pose a danger to patients or damage Plaintiff's reputation.

11. In response to the allegations of paragraph 11 of the First Amended Complaint, IMS denies that it reconstructs endoscopes and denies that the photographs in Exhibit C show optical components contained within a transparent tube of shrunk material. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11 and therefore denies them.

12. In response to the allegations of paragraph 12 of the First Amended Complaint, IMS denies that it reconstructs endoscopes and denies that the photographs in Exhibit D show optical components contained within a transparent tube of shrunk material, that the illumination of the tube shown in the photographs in Exhibit D shows that the positions of optical components are visible within the tube or that the material of the tube is "see-through." IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12 and therefore denies them.

13. In response to the allegations of paragraph 13 of the First Amended Complaint, IMS denies that it reconstructs endoscopes and denies that the photographs in Exhibit E show optical components contained within a transparent

tube of shrunk material. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13 and therefore denies them.

14. In response to the allegations of paragraph 14 of the First Amended Complaint, IMS denies that it reconstructs endoscopes. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 14 and therefore denies them.

15. In response to the allegations of paragraph 15 of the First Amended Complaint, IMS denies that it reconstructs endoscopes and denies that the photographs in Exhibit G show optical components contained within a transparent tube of shrunk material, that illumination of the tube shown in the photographs in Exhibit G shows that the positions of optical components are visible within the tube or that the material of the tube is “see-through.” IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 15 and therefore denies them.

16. In response to the allegations of paragraph 16 of the First Amended Complaint, IMS denies that it reconstructs endoscopes and denies that the photographs in Exhibit H show rod lenses contained within a transparent tube of shrunk material. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 16 and therefore denies them.

17. IMS denies the allegations of paragraph 17 of the First Amended Complaint.

18. IMS denies the allegations of paragraph 18 of the First Amended Complaint.

19. In response to the allegations of paragraph 19 of the First Amended Complaint, IMS denies that it reconstructs endoscopes, that it has modified endoscopes to be of inferior quality or that it has tarnished Plaintiff's reputation. IMS lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 and therefore denies them.

20. In response to the allegations of paragraph 20 of the First Amended Complaint, IMS admits that it received a letter dated March 12, 2009 which enclosed U.S. Publication No. 2006/0041187, which later matured into the '945 patent. IMS denies the remaining allegations of paragraph 20.

21. IMS denies the allegations of paragraph 21 of the First Amended Complaint.

22. In response to the allegations of paragraph 22 of the First Amended Complaint, IMS admits that Plaintiff filed its initial Complaint in this action on August 15, 2012, that IMS filed two *inter partes* reexamination requests with the USPTO seeking reexamination of the '945 Patent and the '437 Patent, that this case was stayed following the filing of those reexamination requests and that the USPTO

denied the request for reexamination of the claims of the '945 Patent and claims 1-7 of the '437 Patent, but IMS states that the USPTO ordered reexamination of claims 8-14 of the '437 Patent. IMS denies any remaining allegations of paragraph 22.

23. In response to the allegations of paragraph 23 of the First Amended Complaint, IMS admits that the USPTO issued an *Inter Partes* Reexamination Certificate relating to the '437 Patent on May 26, 2017, that claims 8-13, as amended during reexamination, were determined to be patentable, that claim 14 was determined to be patentable and that claims 15-21 added during reexamination were rejected. IMS denies any remaining allegations of paragraph 23.

24. IMS admits the allegations of paragraph 24 of the First Amended Complaint.

Count I – Infringement of U.S. Patent No. 7,530,945

25. In response to the allegations of paragraph 25 of the First Amended Complaint, IMS incorporate its responses to paragraphs 1-24 above.

26. IMS denies the allegations of paragraph 26 of the First Amended Complaint.

27. IMS denies the allegations of paragraph 27 of the First Amended Complaint.

28. IMS denies the allegations of paragraph 28 of the First Amended Complaint.

29. In response to the allegations of paragraph 29 of the First Amended Complaint, IMS states that it does not utilize a transparent and shrinkable material as claimed in the '945 patent. IMS further denies that the '945 Patent claims materials which are see-through to permit visual inspection of the optical components inside as alleged in paragraph 29. Rather, the '945 Patent claims only transparent materials, the plain meaning of which as the PTAB has held is "having the property of transmitting light without appreciable scattering so that bodies lying beyond are seen clearly" and does not encompass translucent materials, the plain meaning of which the PTAB has held is "permitting the passage of light; especially transmitting and diffusing light so that objects beyond cannot be seen clearly." IMS denies any remaining allegations of paragraph 29.

30. IMS denies the allegations of paragraph 30 of the First Amended Complaint.

31. IMS denies the allegations of paragraph 31 of the First Amended Complaint.

32. IMS denies the allegations of paragraph 32 of the First Amended Complaint.

Count II – Infringement of U.S. Patent No. RE47,044

33. In response to the allegations of paragraph 33 of the First Amended Complaint, IMS incorporate its responses to paragraphs 1-32 above.

34. The Court has dismissed Count II of the First Amended Complaint as it relates to claims 15-32 of the '044 Patent, and so no response is required to allegations of infringement of those claims.

35. IMS denies the allegations of paragraph 34 of the First Amended Complaint.

36. IMS denies the allegations of paragraph 35 of the First Amended Complaint.

37. IMS denies the allegations of paragraph 36 of the First Amended Complaint.

38. In response to the allegations of paragraph 37 of the First Amended Complaint, IMS states that it does not utilize a transparent material as claimed in the '044 patent. IMS further denies that the '044 Patent claims materials which are see-through to permit visual inspection of the optical components inside as alleged in paragraph 37. Rather, the '044 Patent is limited to transparent materials, the plain meaning of which the PTAB has held is "having the property of transmitting light without appreciable scattering so that bodies lying beyond are seen clearly" and does not encompass translucent materials, the plain meaning of which the PTAB has held is "permitting the passage of light; especially transmitting and diffusing light so that objects beyond cannot be seen clearly." IMS denies any remaining allegations of paragraph 37.

39. In response to the allegations of paragraph 38 of the First Amended Complaint, IMS states that Count II has been dismissed as it relates to claims 15 and 23 asserted in paragraph 38. Notwithstanding that dismissal, IMS denies the allegations of paragraph 38.

40. IMS denies the allegations of paragraph 39 of the First Amended Complaint.

41. IMS denies the allegations of paragraph 40 of the First Amended Complaint.

42. IMS denies the allegations of paragraph 41 of the First Amended Complaint.

Prayer for Relief

43. IMS denies all allegations contained in Plaintiff's Prayer for Relief, denies any liability to Plaintiff, denies that Plaintiff is entitled to any relief from IMS.

Jury Demand

44. IMS respectfully requests a trial by jury on all issues so triable.

Additional Defenses

45. To the extent that any allegations in the First Amended Complaint have not been specifically admitted, IMS denies them.

46. The First Amended Complaint fails to state a claim upon which relief may be granted.

47. IMS has not infringed, and does not infringe, under any theory of infringement, any valid, enforceable claim of the '945 or '044 Patents that remains in this action, whether directly, indirectly, through the doctrine of equivalents or otherwise, and is not inducing and has not induced others to infringe any claim of either the '945 or '044 Patents that remains in this action.

48. To the extent Plaintiff alleges indirect infringement, IMS is not and has not knowingly caused indirect infringement by any third party of any valid and enforceable claim of either the '945 or '044 Patents that remains in this action.

49. The claims of the '945 and '044 Patents that remain in this action are invalid for failure to comply with one or more of the statutory requirements set forth in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

50. On information and belief, Plaintiff's claims for recovery are barred or limited, in whole or in part, prior to the date on which IMS received actual notice of Plaintiff's allegations of infringement, including under 35 U.S.C. § 287.

51. Plaintiff's claims are barred, in whole or in part, based on the doctrine of exhaustion because Plaintiff's sale of the endoscopes allegedly repaired by IMS exhausted Plaintiff's patent rights.

52. Plaintiff's claims are barred, in whole or in part, because any repair of endoscopes conducted by IMS constitutes permissible repair of such products.

53. Plaintiff's claims are barred, in whole or in part, based upon prosecution history estoppel or prosecution history disclaimer.

54. Plaintiff's claims are barred, in whole or in part, by equitable doctrines, including estoppel and unclean hands.

55. IMS expressly reserves the right to assert any other legal or equitable defenses to which it is shown to be entitled, including all affirmative defenses under Fed. R. Civ. P. 8(c), the Patent Laws of the United States, and any other defenses that may now exist or in the future be available based upon discovery or further factual investigations in this case.

WHEREFORE, IMS respectfully requests the following relief:

- a. A judgment in its favor dismissing the First Amended Complaint, with prejudice;
- b. A judgment that this case is exceptional under 35 U.S.C. § 285;
- c. A judgment awarding its costs and attorneys' fees; and
- d. A judgment awarding IMS such other relief as the Court deems just, equitable and proper.

IMS' COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., STERIS Instrument Management Services, Inc., f/k/a Integrated Medical Systems International, Inc.

(“IMS”), as Counterclaim-Plaintiff, asserts its counterclaims against Counterclaim-Defendant Karl Storz Endoscopy-America, Inc. (“Storz”) as follows:

PARTIES

1. IMS is a Delaware corporation with its principal place of business located at 3316 2nd Avenue North, Birmingham, Alabama 35222.
2. On information and belief, Storz is a California corporation with its principal place of business in El Segundo, California.

JURISDICTION AND VENUE

3. Subject matter jurisdiction over these counterclaims arises under the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, and the laws of the United States concerning jurisdiction of actions arising under the patent laws of the United States, 28 U.S.C. § 1338(a).

4. Storz has consented to venue in this judicial district by filing its First Amended Complaint against IMS in this district alleging infringement of U.S. Patent No. 7,530,945 (“the ’945 Patent”) and U.S. Reissued Patent No. RE47,044 (“the ’044 Patent”).

5. A justiciable controversy has arisen between IMS and Storz with respect to the ’945 and ’044 Patents.

FIRST COUNTERCLAIM
(Declaration of Non-Infringement of the ’945 Patent)

6. IMS realleges and incorporates by reference the allegations in paragraphs 1 through 5 of its Counterclaims above.

7. IMS has not infringed and does not infringe, either directly or indirectly, the claims of the '945 Patent, including claim 1, the only claim which the First Amended Complaint accuses IMS of infringing.

8. Claim 1 of the '945 Patent is as follows:

1. A method for assembling an endoscope having a tubular shaft, an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft, said components of said optical systems are at least partially surrounded by a tube made of both a transparent and a shrunk material, said method comprising the following steps
 - a) introducing said components into a tube of transparent and shrinkable material to form a unit,
 - b) shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another,
 - c) checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube and
 - d) introducing said unit composed of said shrunk tube and said components contained therein into said tubular shaft.

9. IMS incorporates by reference its denials set forth above in its responses to paragraphs 3, 5, 7, 9-21 and 25-32 of the First Amended Complaint.

10. IMS does not infringe claim 1 of the '945 Patent because it does not practice any of steps a) through d) of claim 1.

11. The remaining claims of the '945 Patent depend on claim 1, and so IMS does not infringe any of those claims at least for the reason that it does not infringe claim 1.

12. Absent a declaration that IMS does not infringe the '945 Patent, Storz will continue to wrongfully assert the '945 Patent against IMS in violation of the laws and contrary to the public policy of the United States of America and will thereby continue to cause IMS irreparable injury and damage. A decree by this Court with respect to the issue of non-infringement of the claims of the '945 Patent, as between IMS and Storz, is reasonably calculated to prevent needless additional litigation between IMS and Storz.

13. For the foregoing reasons, there is an actual and justiciable controversy between IMS on the one hand, and Storz on the other, and IMS is entitled to a decree of non-infringement of the claims of the '945 Patent.

SECOND COUNTERCLAIM
(Invalidity of the '945 Patent)

14. IMS realleges and incorporates by reference the allegations in paragraphs 1 through 13 of its Counterclaims above.

15. Claims 1-7 of the '945 Patent are invalid for failure to comply with one or more of the statutory requirements set forth in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

16. The claims of the '945 Patent are not new or nonobvious in view of what was known in the prior art including, for example, the following references, alone or in combination: U.S. Patent No. 5,419,313; U.S. Patent No. 6,398,723; U.S. Patent No. 6,201,649; and the admitted prior art in the '945 Patent.

17. The claims of the '945 Patent are also invalid under 35 U.S. C. § 112 for failure to provide an adequate written description, lack of enablement, and indefiniteness, at least under Storz's apparent application of the claims. For example, at least as alleged by Storz in the First Amended Complaint, the claim term "transparent material" is indefinite. A person of ordinary skill in the art would be unable to ascertain the scope of this term with any reasonable certainty.

18. Absent a declaration that the claims of the '945 Patent are invalid, Storz will continue to wrongfully assert the '945 Patent against IMS in violation of the laws and contrary to the public policy of the United States of America and will thereby continue to cause IMS irreparable injury and damage. A decree by this Court with respect to the issue of invalidity of the claims of the '945 Patent is reasonably calculated to prevent needless additional litigation between IMS and Storz.

19. For the foregoing reasons, there is an actual and justiciable controversy between IMS on the one hand, and Storz on the other, and IMS is entitled to a decree of invalidity of the claims of the '945 Patent.

THIRD COUNTERCLAIM
(Declaration of Non-Infringement of Claims 1-14 of the '044 Patent)

20. IMS realleges and incorporates by reference the allegations in paragraphs 1 through 19 of its Counterclaims above.

21. IMS has not infringed and does not infringe, either directly or indirectly, claims 1-14 of the '044 Patent, including claim 1, the only claim which the First Amended Complaint accuses IMS of infringing.

22. Claim 1 of the '044 Patent is as follows:

1. An endoscope comprising:
a tubular shaft, having an inside face
an optical system having several components, said
components of said optical system are contained in an
interior of said tubular shaft,
said components comprising at least two of the following: a
lens, a spacer, a diaphragm, a prism and a filter, said
components directly surrounded by a support piece made
of shrunk material, wherein
said shrunk material is a transparent material,
said support piece made of said transparent material has a
shape of a tube, and
said tube containing said components of said optical system
has been shrunk prior to inserting said tube into said
interior of said tubular shaft, for allowing a visual check
of a position of said components relative to one another,
and
a gap located between an outside surface of said tube of
shrunk material and said inside face of said tubular shaft.

23. IMS incorporates by reference its denials set forth above in its responses to paragraphs 3, 5, 8-24 and 33-41 of the First Amended Complaint.

24. IMS does not infringe claim 1 of the '044 Patent at least because the accused endoscopes do not include a support piece made of a transparent shrunk material, as required by claim 1.

25. Claims 2-7 of the '044 Patent depend on claim 1, and so IMS does not infringe any of those claims at least for the reason that it does not infringe claim 1.

26. IMS does not infringe claim 8 of the '044 Patent because, like claim 1, claim 8 requires a support piece made of a transparent shrunk material.

27. Claims 9-14 of the '044 Patent depend, directly or indirectly, on claim 8, and so IMS does not infringe any of those claims at least for the reason that it does not infringe claim 8.

28. Absent a declaration that IMS does not infringe claims 1-14 of the '044 Patent, Storz will continue to wrongfully assert claims 1-14 the '044 Patent against IMS in violation of the laws and contrary to the public policy of the United States of America and will thereby continue to cause IMS irreparable injury and damage. A decree by this Court with respect to the issue of non-infringement of claims 1-14 of the '044 Patent, as between IMS and Storz, is reasonably calculated to prevent needless additional litigation between IMS and Storz.

29. For the foregoing reasons, there is an actual and justiciable controversy between IMS on the one hand, and Storz on the other, and IMS is entitled to a decree of non-infringement of claims 1-14 of the '044 Patent.

FOURTH COUNTERCLAIM
(Invalidity of the '044 Patent)

30. IMS realleges and incorporates by reference the allegations in paragraphs 1 through 29 of its Counterclaims above.

31. Claims 1-32 of the '044 Patent are invalid for failure to comply with one or more of the statutory requirements set forth in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

32. The claims of the '044 Patent are not new or nonobvious in view of what was known in the prior art including, for example, the following references, alone or in combination: U.S. Patent No. 5,419,313; U.S. Patent No. 6,398,723; U.S. Patent No. 6,201,649; U.S. Patent Application Publication No. 2006/0041187; and the admitted prior art in the '044 and '945 Patents.

33. The claims of the '044 Patent are also invalid under 35 U.S. C. § 112 for failure to provide an adequate written description, lack of enablement, and indefiniteness. For example, at least as alleged by Storz in the First Amended Complaint, the claim terms “transparent material,” “material of the tube [which] permits a visual check of a position of said components relative to one another,” and “shrunk material [which] permits visual inspection of said plurality of components relative to each other through the shrunk material” are indefinite. A person of ordinary skill in the art would be unable to ascertain the scope of this term with any reasonable certainty.

34. Absent a declaration that the claims of the '044 Patent are invalid, Storz will continue to wrongfully assert the '044 Patent against IMS in violation of the laws and contrary to the public policy of the United States of America and will thereby continue to cause IMS irreparable injury and damage. A decree by this Court with respect to the issue of invalidity of the claims of the '044 Patent is reasonably calculated to prevent needless additional litigation between IMS and Storz.

35. For the foregoing reasons, there is an actual and justiciable controversy between IMS on the one hand, and Storz on the other, and IMS is entitled to a decree of invalidity of the claims of the '044 Patent.

PRAYER FOR RELIEF

WHEREFORE, IMS respectfully asks this Court to enter judgment in its favor and against Storz and grant the following relief.

- A. A declaration that IMS has not infringed and is not infringing, under any theory, any claim of the '945 Patent or claims 1-14 of the '044 Patent, including that it does not and has not infringed literally or under the doctrine of equivalents, and that IMS induced and is not inducing infringement of any claim of the '945 Patent or claims 1-14 of the '044 Patent;
- B. A declaration that the claims of the '945 Patent and the '044 Patent are invalid;

- C. A judgment against Storz and in favor of IMS without any recovery to Storz;
- D. A finding that this case is exceptional and an award to IMS of its reasonable attorney fees and costs pursuant; and
- E. Any and all such further and other relief as the Court may deem proper and just.

Respectfully submitted,

s/ Robert R. Baugh

Robert R. Baugh (ASB-0312-A64R)

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CERTIFICATE OF SERVICE

I hereby certify on July 25, 2019, I electronically filed the foregoing pleading with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following counsel of record in this matter:

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